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the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

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§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

50.1 Authority.

50.2 Exchange Visitor Waiver Review Board.

50.3 Policy.

50.4 Waivers for research.

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50.6 Procedures for submission of application to HHS.

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50.8 Compliance.

AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 et seq.); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the Department of State to recommend to the Attorney General waiver of the two-year foreign residence requirement for Exchange Visitors under the Mutual

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Educational and Cultural Exchange Program. HHS eligibility requirement criteria for waivers are in addition to and independent of the existing waiver and visa criteria established by the Immigration and Naturalization Service (INS), the Department of State, and the Department of Labor. The waiver regulations described in this part do not relieve alien physicians seeking a waiver of the 2-year foreign residence requirement from complying with the terms and conditions imposed on their admission to the United States.

[67 FR 77695, Dec. 19, 2002]

§ 50.2 Exchange Visitor Waiver Review Board.

(a) *Establishment.* The Exchange Visitor Waiver Review Board is established to carry out the Department's responsibilities under the Exchange Visitor Program.

(b) *Functions.* The Exchange Visitor Waiver Review Board is responsible for making thorough and equitable evaluations of applications submitted by institutions, acting on behalf of Exchange Visitors, to HHS for a favorable recommendation to the Department of State that the two-year foreign residence requirement for Exchange Visitors under the Exchange Visitor Program be waived.

(c) *Membership.* The Exchange Visitor Waiver Review Board consists of no fewer than three members and two alternates, of whom no fewer than three will consider any particular application. The Director of the Office of Global Health Affairs, Office of the Secretary, is an ex officio member of the Board and serves as its Chairman. The Director may designate a staff member of the Office of the Secretary to serve as member and Chairman of the Board in the Director's absence. The Assistant Secretary for Health appoints two regularly assigned members and two alternates to consider applications concerning health, biomedical research, and related fields. The Chairman may request the heads of operating divisions of the Department to appoint additional members to consider applications in other fields of interest to the Department. The Board may obtain expert advisory opinions from other sources. The Board may es-

tablish a workgroup from the operating divisions of the Department to consider applications for waivers based on the need for the delivery of health care services to underserved populations.

[49 FR 9900, Mar. 16, 1984, as amended at 67 FR 77695, Dec. 19, 2002]

§ 50.3 Policy.

(a) *Policy for waivers.* The Department of Health and Human Services endorses the philosophy that Exchange Visitors are committed to return home for at least two years after completing their program. This requirement was imposed to prevent the Program from becoming a stepping stone to immigration and to ensure that Exchange Visitors make available to their home countries their new knowledge and skills obtained in the United States. The Department will request waivers for the delivery of health care service to carry out the Department's mission to increase access to care for the nation's most medically underserved individuals. However, in keeping with the philosophy of the Program, the Exchange Visitor Waiver Review Board may determine the appropriate numbers and geographic areas for waivers for the delivery of health care service.

(b) *Criteria for waivers.* The Exchange Visitor Waiver Review Board carefully applies stringent and restrictive criteria to its consideration of requests that it support waivers for Exchange Visitors. Each application is evaluated individually based on the facts available.

(c) *Waiver for members of Exchange Visitor's family.* Where a decision is made to request a waiver for an Exchange Visitor, a waiver will also be requested for the spouse and children, if any, if they have J-2 visa status. When both members of a married couple are Exchange Visitors in their own right (*i.e.*, each has J-1 visa status), separate applications must be submitted for each of them.

[67 FR 77696, Dec. 19, 2002]

§ 50.4 Waivers for research.

In determining whether to request a waiver for an Exchange Visitor engaged in the conduct of research, the

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Board considers the following key factors:

(a) The program or activity at the applicant institution or organization in which the Exchange Visitor is employed must be of high priority and of national or international significance in an area of interest to the Department.

(b) The Exchange Visitor must be needed as an integral part of the program or activity, or of an essential component thereof, so that loss of his/her services would necessitate discontinuance of the program, or a major phase of it. Specific evidence must be provided on how the loss or unavailability of the individual's services would adversely affect the initiation, continuance, completion, or success of the program or activity. The applicant organization/institution must clearly demonstrate that a suitable replacement for the Exchange Visitor cannot be found through recruitment or any other means. The Board will not request a waiver when the principal problem appears to be one of administrative, budgetary, or program inconvenience to the institution or other employer.

(c) The Exchange Visitor must possess outstanding qualifications, training and experience well beyond the usually expected accomplishments at the graduate, postgraduate, and residency levels, and must clearly demonstrate the capability to make original and significant contributions to the program. The Board will not request a waiver simply because an individual has specialized training or experience or is occupying a senior staff position in a university, hospital, or other institution.

[67 FR 77696, Dec. 19, 2002]

§ 50.5 Waivers for the delivery of health care service.

In determining whether to request a waiver for an Exchange Visitor to deliver health care service, the Board will consider information from and coordinate with State Departments of Public Health (or the equivalent), other "interested government agencies" which request waivers, and other relevant agencies. The Board requires the following criteria for requests for

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waivers for the delivery of health care service:

(a) The Exchange Visitor must submit a statement that he or she does not have pending and will not submit any other "interested government agency" waiver request while HHS processes the waiver request being submitted.

(b) Waivers are limited to primary care physicians and general psychiatrists who have completed their primary care or psychiatric residency training programs no more than 12 months before the date of commencement of employment under the contract described in subparagraph (d). This 12-month eligibility limitation is to ensure that the physicians' primary care training is current and they are not engaged in subspecialty training. This HHS eligibility requirement relates only to eligibility for an HHS waiver request and does not relieve physicians of the responsibility to maintain lawful status. Alien physicians are strongly encouraged to begin the waiver process as early as they possibly can while still in the residency training program. Early filing of the waiver request by the alien physician, coupled with timely processing of the request by the relevant government agencies, will facilitate the timely completion of the waiver process before the authorized J-1 admission expires, and the physician's subsequent application for change of nonimmigrant status from J-1 to H-1B.

(c) Primary care physicians are defined as: physicians practicing general internal medicine, pediatrics, family practice or obstetrics/gynecology willing to work in a primary care Health Professional Shortage Area (HPSA) or Medically Underserved Area or Population (MUA/P); and general psychiatrists who are willing to work in a Mental Health HPSA. Note: these HHS eligibility criteria for waivers are in addition to and independent of the existing waiver and visa criteria established by the Immigration and Naturalization Service (INS), the Department of State, and the Department of Labor.

(d) The Exchange Visitor must have entered a contract with the applicant employer. This contract must:

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(1) Require the Exchange Visitor to provide primary medical care in a facility physically located in an HHS-designated primary care HPSA or MUA/P, or general psychiatric care in a Mental Health HPSA.

(2) Require the Exchange Visitor to complete a term of employment of not less than three years providing primary care health services for not less than 40 hours per week.

(3) Require the Exchange Visitor to:

(i) Be licensed by the State where he or she will practice;

(ii) Have completed a residency in one of the following specialties: family practice, general pediatrics, obstetrics/gynecology, general internal medicine, or general psychiatry; and

(iii) Be either board certified or board eligible in the relevant primary care discipline.

(4) Be terminable only for cause until completion of the three-year commitment, except that, with the agreement of the alien physician, the employer may assign the contract to another eligible employer with the prior approval of HHS and compliance with all applicable INS and Department of Labor requirements. Prior to approving an assignment of the contract, HHS will review and consider the health care needs of the alien physician's current and proposed new locations, as well as the reasons for the request.

(5) Not contain a restrictive covenant or non-compete clause which prevents or discourages the physician from continuing to practice in any HHS-designated primary care HPSA or MUA/P or Mental Health HPSA after the period of obligation under the contract has expired.

(6) Provide that any amendment to the contract complies with all applicable Federal statutes, regulations and HHS policy.

(7) Be consistent with all applicable Federal statutes, regulations and HHS policy.

(e) The facility or practice sponsoring the physician:

(1) Must provide health services to individuals without discriminating against them because either they are unable to pay for those services or payment for those health services will be made under Medicare or Medicaid.

(2) May charge no more than the usual and customary rate prevailing in the geographic area in which the services are provided.

(3) Must provide care on a sliding fee scale for persons at or below 200 percent of poverty income level. Persons with third-party insurance may be charged the full fee for service.

(4) Must post a notice in a conspicuous location in the patient waiting area at the practice site to notify patients of the charges for service as required in this paragraph.

(5) Must provide evidence that the applicant facility made unsuccessful efforts to recruit a physician who is a United States physician for the position to be filled by the Exchange Visitor.

(6) Must provide a statement by the head of the facility to confirm the facility is located in a specific, designated HPSA or MUA/P, and that it provides medical care to Medicaid and Medicare eligible patients and to the uninsured indigent.

(f) The employer and the alien physician must submit information to the Secretary at the times and in the manner that the Secretary may reasonably require.

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§ 50.6 Procedures for submission of application to HHS.

(a) The Exchange Visitor Waiver Review Board will review applications submitted by private or non-federal institutions, organizations, or agencies or by a component agency of HHS. The Board will not accept applications submitted by Exchange Visitors or, unless under extenuating and exceptional circumstances, other U.S. Government Agencies.

(b) Applications, instruction sheets and information are available from the Executive Secretary, Exchange Visitor Waiver Review Board. An authorized official of the applicant institution (educational institution, hospital, laboratory, corporation, etc.) must sign the completed application. The applicant institution must send the completed application to the address indicated on the instruction sheet.

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§ 50.7 Personal hardship, persecution and visa extension considerations.

(a) It is *not* within the Department's jurisdiction to consider applications for waiver based on:

(1) Exceptional hardship to the exchange visitor's American or legally resident alien spouse or child; or

(2) The alien's unwillingness to return to the country of his/her nationality or last residence on the grounds that he/she or family members would be subject to persecution on account of race, religion or political opinion.

(b) Likewise, this Department is not responsible for considering requests to extend visas.

(c) Inquiries concerning the above should be directed to the District Office of the Immigration and Naturalization Service which has jurisdiction over the exchange visitor's place of residence in the United States.

[49 FR 9900, Mar. 16, 1984. Redesignated at 67 FR 77696, Dec. 19, 2002]

§ 50.8 Compliance.

If an alien physician acquires H-1B nonimmigrant status following approval by the INS of a request for waiver, then he or she becomes subject not only to the terms and conditions of the waiver, but also the terms and conditions of the H-1B nonimmigrant status. Failure to comply with those conditions will make that physician subject to removal from the United States by the INS.

[67 FR 77697, Dec. 19, 2002]

PART 51—CRITERIA FOR EVALUATING COMPREHENSIVE PLAN TO REDUCE RELIANCE ON ALIEN PHYSICIANS

Sec.

51.1 Purpose.

51.2 Application.

51.3 Who is eligible to apply?

51.4 How will the plans be evaluated?

AUTHORITY: Sec. 212, Immigration and Nationality Act, Pub. L. 82-114, as amended by Pub. L. 97-116, 95 Stat. 1611 (8 U.S.C. 1182(j)(2)(A)).

SOURCE: 48 FR 2539, Jan. 20, 1983, unless otherwise noted.

45 CFR Subtitle A (10-1-10 Edition)

§ 51.1 Purpose.

The purpose of this regulation is to establish criteria for review and evaluation of the comprehensive plans of Graduate Medical Education Programs to reduce reliance on alien physicians, as required by the Immigration and Nationality Act Amendments of 1981, Pub. L. 97-116, for the waiver of certain requirements for exchange visitors who are coming to the United States to participate in programs of graduate medical education or training.

§ 51.2 Application.

Materials covering procedures for applying for substantial disruption waivers (including the comprehensive plan) may be obtained from the Educational Commission for Foreign Medical Graduates, 3624 Market Street, Philadelphia, Pennsylvania 19104.

EXPLANATORY NOTE: The Department of State entered into an agreement with the Educational Commission for Foreign Medical Graduates in 1971 whereby the latter was designated the authority to administer the issuance of the Form IAP-66 in all cases involving the admission, certification, transfer or extension of stay for foreign physicians in exchange visitor status who are receiving graduate medical education or training. The Commission was further designated the authority (FEDERAL REGISTER, Volume 44, No. 59, March 26, 1979), to process waiver requests under the "substantial disruption" provision of Pub. L. 94-484, as amended, within criteria to be provided by the United States Information Agency on advice from the Department of Health and Human Services (formerly Department of Health, Education, and Welfare).

§ 51.3 Who is eligible to apply?

Sponsors which had alien physicians in their exchange visitor programs on January 10, 1978, are eligible to apply. For purposes of this regulation, the term "program" relates to a graduate medical education program having an exchange visitor program for physicians participating in graduate medical education or training. An "exchange visitor program" is a program of a sponsor, designed to promote interchange of persons, knowledge and skills, and the interchange of developments in the field of education, the arts and sciences, and is concerned